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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/588,888

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Drew Pardoll

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EXAMINER

GIBBS, TERRA C

ART UNIT

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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/588,888	<b>Applicant(s)</b> PARDOLL ET AL.	
	<b>Examiner</b> TERRA C. GIBBS	<b>Art Unit</b> 1635	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 8 October 2010.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-36 is/are pending in the application.
- 4a) Of the above claim(s) 1-19 and 23-31 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 34 are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |   |   |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                    | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)         | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____   | 6) <input type="checkbox"/> Other: _____                          |

### **DETAILED ACTION**

This Office Action is a response to Applicant's Amendment and Remarks filed October 8, 2010.

Claims 1-36 are pending in the instant application.

Claims 1, 20, and 34 have been amended.

Applicant's election, without traverse, of Group III, claims 20-22 and 32-36 in the reply filed on March 22, 2010 is acknowledged. Accordingly, claims 1-19 and 23-31 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim.

Accordingly, claims 20-22 and 32-36 have been examined on the merits. However, after careful consideration of Applicant's Amendment to the claims filed October 8, 2010, claim 34 is subject to restriction requirement as detailed below:

### ***Election/Restrictions***

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claim 34, drawn to a population of dendritic cell for use in vaccination of a subject produced by the process of (a) obtaining dendritic cells from an individual, (b) causing the dendritic cells to express an antigen by either (i) exposing the dendritic cells to the antigen in culture under conditions promoting uptake and processing of the antigen, or (ii) transfecting the dendritic cells with a gene encoding the antigen; (c) activating the antigen-expressing dendritic cells, (d) treating the dendritic cells with an agent that inhibits MINOR expression, wherein the agent that inhibits MINOR

expression is a peptide or peptidomimetic, classifiable in class 424, subclass 134.1, for example.

- II. Claim 34, drawn to a population of dendritic cell for use in vaccination of a subject produced by the process of (a) obtaining dendritic cells from an individual, (b) causing the dendritic cells to express an antigen by either (i) exposing the dendritic cells to the antigen in culture under conditions promoting uptake and processing of the antigen, or (ii) transfecting the dendritic cells with a gene encoding the antigen; (c) activating the antigen-expressing dendritic cells, (d) treating the dendritic cells with an agent that inhibits MINOR expression, wherein the agent that inhibits MINOR expression is small molecule, classifiable in class 514, subclass 2, for example.
- III. Claim 34, drawn to a population of dendritic cell for use in vaccination of a subject produced by the process of (a) obtaining dendritic cells from an individual, (b) causing the dendritic cells to express an antigen by either (i) exposing the dendritic cells to the antigen in culture under conditions promoting uptake and processing of the antigen, or (ii) transfecting the dendritic cells with a gene encoding the antigen; (c) activating the antigen-expressing dendritic cells, (d) treating the dendritic cells with an agent that inhibits MINOR expression, wherein the agent that inhibits MINOR expression is an inhibitory nucleotide, classifiable in class 536, subclass 24.5, for example.

The inventions are distinct, each from the other because of the following reasons:

Searching the inventions of Groups I-III together would impose a serious search burden. Although the methods of Groups I-III are related because they involve a population of dendritic cell for use in vaccination of a subject produced by the process of (a) obtaining dendritic cells from an individual, (b) causing the dendritic cells to express an antigen by either (i) exposing the dendritic cells to the antigen in culture under conditions promoting uptake and processing of the antigen, or (ii) transfecting the dendritic cells with a gene encoding the antigen; (c) activating the antigen-expressing dendritic cells, (d) treating the dendritic cells with an agent that inhibits MINOR expression, they are patentably distinct from each other. Although there are no provisions under the section for "Relationship of Inventions" in MPEP 806.05 for inventive groups that are directed to related compositions, restriction is deemed to be proper because these compositions appear to constitute patentably distinct inventions for the following reasons: They employ the use of different MINOR inhibiting agents with different chemical and physical structures so that independent searches of the prior art would be required that would constitute a serious burden on the Examiner. For example, a search of the peptide MINOR inhibiting agent of Group I would not encompass all of the art relevant to the small molecule MINOR inhibiting agent of Group II or the inhibitory nucleotide MINOR inhibiting agent of Group III. Similarly, a search of the small molecule MINOR inhibiting agent of Group II would not encompass all of the art relevant to the inhibitory nucleotide MINOR inhibiting agent of Group III. They are materially distinct compositions which differ in criteria for success. Thus, they are

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patentably distinct from each other.

Furthermore, searching the inventions of Groups I-III would impose a serious search burden because the inventions of Groups I-III are unrelated, each from the other. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case, the invention of Groups I-III are unrelated and distinct because they are drawn to distinct compositions such that independent searches of the prior art would be required that would constitute a serious burden on the Examiner. For example, a search of the peptide MINOR inhibiting agent of Group I would require a search in the peptide art; while a search of the small molecule MINOR inhibiting agent of Group II would require a search in the small molecule art; while a search of the inhibitory nucleotide MINOR inhibiting agent of Group III would require a search in the nucleic acid art. Since the search for Group I is not entirely coextensive with a search for Groups II and III, and a search of Group II is not entirely coextensive with a search for Group III, it would be burdensome to search the inventions of these Groups together in one application. It is therefore a burden to search the inventions of Groups I-III together in a single application.

Furthermore, the inventions are also therefore not obvious variants (based on the record), and have a materially different design. Therefore, because these Groups are unique and different compositions, the prior art applicable to one Group would not likely be applicable to another Group and the inventions in each Group are likely to raise different non-prior art issues under 35 U.S.C. 101 and/or 35 U.S.C. 112, first paragraph.

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Accordingly, restriction between these Groups is considered proper.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper. Also, because these inventions are independent or distinct for the reasons given above and there would be a serious burden on the Examiner if restriction were not required because the inventions require a different field of search (see MPEP 808.02), restriction for examination purposes as indicated is proper.

Restriction for examination purposes as indicated is proper because all these inventions listed in this action are independent or distinct for the reasons given above and there would be a serious search and examination burden if restriction were not required because one or more of the following reasons apply:

- (a) the inventions have acquired a separate status in the art in view of their different classification;
- (b) the inventions have acquired a separate status in the art due to their recognized divergent subject matter;
- (c) the inventions require a different field of search (for example, searching different classes/subclasses or electronic resources, or employing different search queries);
- (d) the prior art applicable to one invention would not likely be applicable to another invention;
- (e) the inventions are likely to raise different non-prior art issues under 35 U.S.C. 101 and/or 35 U.S.C. 112, first paragraph.

**Applicant is advised that the reply to this requirement to be complete must include (i) an election of a invention to be examined even though the requirement may be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.**

The election of an invention may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse. Traversal must be presented at the time of election in order to be considered timely. Failure to timely traverse the requirement will result in the loss of right to petition under 37 CFR 1.144. If claims are added after the election, applicant must indicate which of these claims are readable on the elected invention.

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If claims are added after the election, applicant must indicate which of these claims are readable upon the elected invention.

Should applicant traverse on the ground that the inventions are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(I).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Terra C. Gibbs whose telephone number is 571-272-0758. The examiner can normally be reached from 9 am - 5 pm M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Heather Calamita can be reached on 571-272-2876. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

December 9, 2010

/Terra Cotta Gibbs/